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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/693,179

10/23/2003

Nael A. Al-Abdulla

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EDWARDS ANGELL PALMER & DODGE LLP

P.O. BOX 55874

BOSTON, MA 02205

EXAMINER

KIDWELL, MICHELE M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/693,179	Applicant(s) AL-ABDULLA ET AL.	
	Examiner Michele Kidwell	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/4/11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-17,19-49 and 51-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-17,19-49 and 51-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 4, 2001 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 3, 5, 7 – 17, 19 – 49 and 51 – 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 4,175,704) in view of Goddard (US 5,059,188).

With respect to claim 1, Cohen discloses a device for the delivery of a substance to the eye comprising: a housing (12) for holding the substance and a non-aerosol, non-electric (abstract) delivery mechanism comprising a tubular member (20) disposed within the housing, an actuation mechanism (30) positioned at the top of the housing, and at least one outlet port (34) in the actuation mechanism in communication with the tubular member, wherein the delivery mechanism is configured such that substance is delivered from the housing, through the tubular member, through the outlet port, and delivered to the eye in the form of a spray or mist in a substantially horizontal direction (figures 2 and 4) as set forth in col. 2, lines 25 – 60 and in the figures.

It is noted that the dimensions as claimed may be equivalent to zero, and therefore do not necessarily need to be present in order to meet the claimed limitations. Further, it is noted that the device need only to be “configured to” provide the dimensions and/or functions as claimed. Nevertheless, Cohen does not explicitly recite maximum dimensions.

Goddard teaches a device for delivering substances to the eye that delivers the substance from nozzle hole opening with a diameter of 1 - 2 mm as set forth in col. 3, lines 23 – 24.

It would have been obvious to one of ordinary skill in the art to modify the nozzle hole opening of Cohen by providing it with the claimed range since the use of such a range to deliver substances to the eye is known in the art as demonstrated by Goddard and, as the instant specification acknowledges that the average ocular area is about 11 mm in diameter, the incorporations of the dimensions taught by Cohen provides for accurate delivery of the substance to the eye.

Regarding claim 2, see the rejection of claim 1. Additionally, Cohen discloses a device for the delivery of an artificial tears or demulcent composition to the eye comprising: a housing (12) for holding the substance and a non-aerosol, non-electric (abstract) delivery mechanism comprising a tubular member (20) disposed within the housing, an actuation mechanism (30) positioned at the top of the housing, and at least one outlet port (34) in the actuation mechanism in communication with the tubular member, wherein the delivery mechanism is configured such that substance is delivered from the housing, through the tubular member, through the outlet port, and ,delivered to the eye in the form of a spray or mist as set forth in col. 2, lines 25 – 60 and in the figures.

The difference between Cohen and claim 2 is the explicit recitation that the outlet port is configured to deliver the substance in an elliptical shape.

Goddard teaches a device for delivering substances to the eye that delivers the substance from nozzle hole opening in an elliptical shape as set forth in figure 4.

It would have been obvious to one of ordinary skill in the art to modify the nozzle hole opening of Cohen by providing it with the shape taught by Goddard since the use of such shape is used to deliver substances to the eye is known in the art as demonstrated by Goddard and the use of such provides for accurate delivery of the substance to the eye.

With reference to claim 3, Cohen discloses a device wherein the force of the spray or mist is sufficient to deliver the spray or mist to the eye without the aid of gravity as set forth in col. 2, lines 61 – 68. The examiner contends that the force is directly related to the amount of pressure applied and may be sufficient to deliver to deliver the spray or mist without the aid of gravity.

As to claim 5, Cohen discloses a device wherein the housing is hollow and the substance is contained within the hollow of the housing as set forth in figure 4.

Regarding claim 7, Cohen discloses a device wherein the housing contains a reservoir that holds the substance as set forth in figures 2 and 4.

As to claims 8 and 9, Cohen discloses a device wherein the housing is fabricated of a rigid material, which would be of sufficient thickness to prevent collapse of the housing during use, as set forth in col. 2, lines 11 – 16.

With respect to claim 10, see col. 2, lines 11 - 12.

With reference to claim 11, Cohen discloses a device wherein the housing is cylindrical in shape as set forth in figure 2.

With respect to claims 12 – 17, see col. 5, lines 5 – 19 of Goddard.

Regarding claims 19 and 20, Cohen discloses a device wherein the actuation mechanism is movable with respect to the housing in order to deliver the substance to the eye as set forth in col. 3, lines 10 – 17. The examiner contends that the manner by which the actuation mechanism is moved is considered a product-by-process limitation that does not patentably distinguish the claimed invention from the prior art.

As to claim 21, Cohen discloses a device wherein the actuation mechanism includes a spray nozzle (34) as set forth in figure 2.

With reference to claims 22 – 23, see the rejection of claims 19 – 21.

Regarding claims 24 – 27, see the abstract.

As to claims 28 – 29 and 32, the examiner contends that Cohen discloses the invention as claimed.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The invention of Burke is fully capable of performing the recited function.

As to claim 30, see col. 2, lines 61 – 68.

Regarding claim 31, see col. 3, lines 10 – 17.

With reference to claim 33, Burke discloses a device further comprising an extension (60) substantially or completely surrounding the outlet port and extending in

the direction that the spray or mist is delivered wherein the extension assists in directing the substance to the eye and assists in preventing the substance from being delivered to areas outside of the eye as set forth in figures 7 – 8.

As to claim 34, see the rejection of claim 3.

As to claim 35, see the rejection of claim 2.

As to claims 36 and 37, see the abstract.

As to claim 38, see the rejection of claim 4.

With reference to claims 39 – 41, see the rejection of claims 19 – 20.

As to claim 42, see col. 3, lines 10 – 17 and the abstract.

With reference to claim 43, see the rejection of claim 27.

With reference to claims 44 – 47, see the rejection of claims 28 – 29 and 32.

As to claim 48, see col. 6, lines 33 – 45.

Regarding claim 49, see the rejection of claims 1 and 2. Likewise, Goddard provides a means that prevents contact with the eye as set forth in figure 7.

As to claims 51 and 52, the examiner contends that any device may be considered reusable and/or disposable.

With reference to claims 53 – 56, see col. 3, lines 51 – 54.

As to claims 57 and 58, see the rejection of claims 1 and 2.

Response to Arguments

Applicant's arguments filed February 4, 2011 have been fully considered but they are not persuasive.

The applicant argues that there is no relationship between the size of the Cohen's nozzle and Goddard's opening. The examiner maintains that Goddard is only relied upon to demonstrate a knowledge in the prior art to provide a device that delivers a substance to the eye with the claimed diameter. There does not have to be a relationship established between the openings of Cohen and Goddard. Each invention provides an opening to allow fluid to be dispersed. Goddard simply provides a knowledge of the prior art to provide the fluid in a certain diameter. Any substance provided through the opening – in the form of a drop or a mist -- is limited by the size of the opening. In this case, Goddard provided an opening that meets the limitations as claimed.

Further, the examiner notes that the dimensions as claimed may be equivalent to zero, and therefore do not necessarily need to be present in order to meet the claimed limitations. Further, it is noted that the device need only to be "configured to" provide the dimensions and/or functions as claimed.

The applicant argues that Goddard does not provide the elliptical shape, however, the examiner disagrees. Elliptical may be defined as an elongated circle. As shown in figures 2 and 4, Goddard provides a number of circles to dispense the drops. Further, if enough solution is dispensed, then the shape of the drop would indeed be altered by the guard. Even further, a change in size or shape of the drop may be considered as an obvious design choice absent a teaching of unexpected result.

Conclusion

This is a continuation of applicant's earlier Application No. 10/693,179. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/
Primary Examiner, Art Unit 3761